UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

SULEIMAN A. REFAEI	:	Civil Action No.: **1:10cv833**
Plaintiff	:	Judge: **Susan J. Dlott**
vs.	:	
VANTAGE ONCOLOGY AND ASSOCIATES, INC.	:	
AKA VANTAGE ONCOLOGY, INC.,	:	**PLAINTIFF'S FIRST AMENDED**
VANTAGE ONCOLOGY, LLC,	:	**COMPLAINT WITH JURY DEMAND**
VANTAGE ONCOLOGY TREATMENT CENTERS, LLC,	:	
VEC GP, LLC,	:	
VALLEY EQUIPMENT CO.,	:	
VANTAGE MEDICAL SERVICES, LLC,	:	
AND STREATOR RADIATION ONCOLOGY, LLC	:	
and	:	
NEELIMA KABRE, M.D.	:	
c/o Vantage Oncology and Associates, Inc.	:	
600 East First Street	:	
Spring Valley, IL 61362	:	
Defendants	:	

Now comes Plaintiff, by and through counsel, and hereby submits this First Amended Complaint asserting a claim for a False Claims Act retaliatory discharge pursuant to 31 U.S.C. §3730(h)

I. JURISDICTION AND VENUE

1. This action arises under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*

2. Jurisdiction over this action is vested in this Court by 31 U.S.C. § 3732(a), 31 U.S.C. § 3730(h), and 28 U.S.C. § 1331, in that this action arises under the laws of the United

States.

3. Venue is proper in this district under 31 U.S.C. § 3732(a). The Defendant Vantage can be found, resides, and transacts business within the district.

II. THE PARTIES AND RELATED ENTITIES

4. Plaintiff states that he is a resident of the State of Ohio. Plaintiff was employed by Vantage from November 2008 through September 8, 2010 at which time Plaintiff was terminated from his employment with Vantage.

5. During the period of his employment Plaintiff worked for Defendant Vantage Oncology, Inc. and its affiliates herein identified as Vantage Oncology, Inc., Vantage Oncology, LLC, Vantage Oncology Treatment Centers, LLC, VEC GP, LLC, Valley Equipment Co., Vantage Medical Services, LLC, and Streator Radiation Oncology, LLC (hereinafter referred to as "Vantage") as a Medical Physicist and performed his job duties in a capable and competent manner.

6. Defendant Vantage is a Delaware corporation incorporated in 2002 with its principal place of business in Manhattan Beach, California. Vantage provides a wide range of patient services including the use of diagnostic and therapeutic radiation treatment for radiation oncology through approximately thirty-four treatment centers located throughout the United States. These treatment centers are located in the following states: Arizona, California, Florida, Illinois, Indiana, Kentucky, Massachusetts, New York, Ohio, Pennsylvania, Rhode Island and Texas. While Plaintiff was employed, his job duties were performed primarily at the Vantage Oncology Centers located in Streator, Illinois ("Streator") and at the Valley Cancer Center in Spring Valley, Illinois ("Spring Valley"). Plaintiff has substantial firsthand knowledge of the

business activities at the Vantage Oncology Imperial Valley Cancer Center in El Centro, California, and South Suburban Cancer Center in Hazel Crest, Illinois. Vantage does business in the Southern District of Ohio at the Eastgate Commerce Center located at 4415 Aicholtz Road in Clermont County, Ohio.

7. Defendant Vantage offers a wide range of radiation oncologist services for those diagnosed with cancer. Radiation therapy involves the use of ionizing radiation to treat many forms of cancer. It can be delivered both internally and externally. The published goal of radiation therapy is to give a cancerous tumor a lethal dose of radiation while limiting the exposure to the surrounding healthy tissue. When treating a patient with radiation, sophisticated dosage calculations are made in order to contour the shape and intensity of the radiation beam or the internal dose precisely to the targeted area.

8. Neelima D. Kabre, M.D. is a physician licensed to practice in the State of Illinois as a Radiation Oncologist. During the relevant period, she has been the Medical Director for both Streator and Spring Valley. She is also the Radiation Safety Officer ("RSO") for both Centers. As the RSO, she is statutorily responsible to create, implement and adopt policies and procedures designed to ensure compliance with all federal, state and industry regulations related to the use, handling, and disposal of radioactive materials and safe use of all generating equipment.

9. Defendant Vantage is a partner/affiliate with the Spring Valley and Streator Centers and with Neelima D. Kabre, M.D.

III. THE LAW

10. 31 U.S.C. § 3730(h)(1) and (2) provide in relevant part:

> "(h) Relief from retaliatory actions.
>
> (1) In general. Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent or associate others in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter [31 USCS §§ 3721, *et seq*.].
>
> (2) Relief. Relief under paragraph (1) shall include reinstatement with the same seniority status that employee, contractor, or agent would have had but for the discrimination, 2 times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees. An action under this subsection may be brought in the appropriate district court of the United States for the relief provided in this subsection."

IV. THE FEDERAL HEALTH CARE PROGRAMS

A. Medicare Part B

11. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare program, to pay for the costs of certain health care services and items. 42 U.S.C. §§ 1395 *et seq*. Health and Human Services ("HHS") is responsible for the administration and supervision of the Medicare program. Centers for Medicare and Medicaid Services ("CMS") is an agency of HHS and directly administers the Medicare program. The Medicare program has several parts, including Medicare Part B ("Supplementary Medical Insurance for Aged and Disabled"). 42 U.S.C. § 1395k; 42 C.F.R. § 410.10.

12. The Medicare Part B program is a 100% federally subsidized health insurance

system for eligible persons aged 65 and older and persons with qualifying disabilities, who may enroll in the program to obtain benefits in return for payments of monthly premiums as established by HHS. The benefits covered by the Medicare Part B program include medical treatment and services by physicians under 42 U.S.C. § 1395k(a)(2)(B) in Illinois, and the other contractors responsible for servicing the Vantage centers in other locations within the United States.

13. The United States provides reimbursement for Medicare claims from the Medicare Trust Fund through CMS. To assist in the administration of Part B of the Medicare program, CMS contracts with "carriers." 42 U.S.C. §1395u. Carriers, typically insurance companies, are responsible for processing the payment of Part B claims to providers on behalf of CMS. *Id.* Wisconsin Physician Service ("WPS") is the carrier responsible for processing the payment of Part B claims to Vantage on behalf of CMS in the State of Illinois. Other carriers are responsible for the processing of payments for the other radiation centers operated by Vantage outside the State of Illinois.

14. At all relevant times herein, Vantage knowingly submitted and caused false claims to be submitted to Medicare through its contractor, WPS.

B. The Medicare Provider Agreement

15. Illinois medical providers claim Medicare Part B reimbursement from WPS pursuant to written provider agreements. WPS receives, processes, and pays or rejects those claims according to Medicare rules, regulations and procedures.

16. Vantage and Kabre signed or caused to be executed provider agreements with Medicare that permitted Vantage to submit claims and accept payment for services provided by

Kabre and Vantage physicians for Medicare patients.

17. Medicare assigns each participating provider a unique billing Provider Identification Number ("PIN"). Vantage submits its Medicare claims via its PIN which it uses at its various treatment centers. Vantage and Kabre submitted enrollment forms identified as CMS-855B and CMS-855I respectively in order to participate in the Medicare plan and to lawfully be permitted to submit claims for charges incurred as a result of treating individuals covered by Medicare. Submission of these enrollment forms permitted both Vantage and Kabre to electronically submit CMS-1500 forms to its carrier, WPS.

18. In order to participate in the Medicare program, Vantage, at its Streator, Spring Valley and all other locations, was required to complete and submit to CMS its enrollment application: CMS-855I. That enrollment application provided:

> "Section 14: Penalties for Falsifying Information
>
> 1. 1.18 U.S.C. § 1001 authorizes criminal penalties against an individual who, in any matter within the jurisdiction of any department or agency of the United States, knowingly and willfully falsifies, conceals or covers up by any trick, scheme or device a material fact, or makes any false, fictitious, or fraudulent statements or representations, or makes any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry. . . .
>
> 2. Section 1128B(a)(1) of the Social Security Act authorizes criminal penalties against any individual who, "knowingly and willfully," makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a Federal health care program. . . .
>
> 3. The Civil False Claims Act, 31 U.S.C. § 3729, imposes civil liability, in part, on any person who:

a) knowingly presents, or causes to be presented, to an officer or any employee of the United States Government a false or fraudulent claim for payment or approval;

b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; or

c) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

The Act imposes a civil penalty of $5,000 to $10,000 per violation, plus three times the amount of damages sustained by the Government.

4. Section 1128A(a)(1) of the Social Security Act imposes civil liability, in part, on any person (including an organization, agency or other entity) that knowingly presents or causes to be presented to an officer, employee, or agent of the United States, or of any department or agency thereof, or of any State agency…a claim…that the Secretary determines is for a medical or other item or service that the person knows or should know:

a) was not provided as claimed; and/or

b) the claim is false or fraudulent. . . .[2]

5. 18 U.S.C. 1035 authorizes criminal penalties against individuals in any matter involving a health care benefit program who knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact; or makes any materially false, fictitious, or fraudulent statements or representations, or makes or uses any materially false fictitious, or fraudulent statement or entry, in connection with the delivery of or payment for health care benefits, items or services. . . .

[2] 18 U.S.C. § 1128(a)(1)(E) prohibits any person from presenting a claim for medical services that a person knows or should know is not medically necessary.

> 6. 18 U.S.C. 1347 authorizes criminal penalties against individuals who knowing and willfully execute, or attempt, to execute a scheme or artifice to defraud any health care benefit program, or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by or under the control of any health care benefit program in connection with the delivery of or payment for health care benefits, items, or services. . .”

19. In light of the foregoing penalties, Vantage, at its Streator, Spring Valley and all other Vantage locations, certified to CMS:

> “Certification Statement
>
> You MUST sign and date the certification statement below in order to be enrolled in the Medicare program. In doing so, you are attesting to meeting and maintaining the Medicare requirements stated below.
>
> . . .
>
> 3. I have read and understand the Penalties for Falsifying Information, as printed in this application. I understand that any deliberate omission, misrepresentation, or falsification of any information contained in this application or contained in any communication supplying information to Medicare, or any deliberate alteration of any text on this application form, may be punished by criminal, civil, or administrative penalties including, but not limited to, the denial or revocation of Medicare billing privileges, and/or the imposition of fines, civil damages, and/or imprisonment.
>
> 4. I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to the organization listed in Section 4A of this application. The Medicare laws, regulations, and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier’s compliance with all applicable conditions of participation in Medicare.

. . .

> 8. I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity."

20. Dr. Kabre executed a CMS-855B Medicare Enrollment Application. That application provided the same language as a penalty for falsifying information as that is identified in the CMS-855I for Vantage. The CMS-855B contained the same certifications as the CMS-855I.

21. Vantage and a physician who treats a Medicare patient is required to submit an electronic or hard-copy Medicare Health Insurance Claim Form ("HCFA form 1500") to the carrier, who on behalf of CMS, pays a portion of the claim. In submitting Medicare claim forms, providers must certify that the information included on the form presents an accurate description of the services rendered and that the services were medically necessary.

22. In particular, Vantage and Kabre certified to the following language on the CMS-1500 enrollment form that they submitted to Medicare: "I certify that the services shown on this form were medically indicated and necessary for the health of the patient . . . ."

> "NOTICE: This is to certify that the foregoing information is true, accurate and complete. I understand that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws."

23. By participating in the hard copy and computerized billing of Medicare claims, Vantage physicians agreed to submit claims using HCFA form 1500 and were aware of the required certifications.

C. The TRICARE Program

24. TRICARE, formerly known as CHAMPUS, is a federal health benefits program, established by 10 U.S.C. §§ 1071-1110, that offers a triple option benefit plan: an HMO option; a PPO option; and a fee for service option. TRICARE/CHAMPUS is administered by the Secretary of Defense. TRICARE/CHAMPUS provides health care benefits to eligible beneficiaries, which include, among others, active duty service members, retired service members, and their dependents.

25. The regulatory authority establishing the TRICARE/CHAMPUS program provides reimbursement to individual health care providers applying the same reimbursement scheme and coding parameters that the Medicare program applies. 10 U.S.C. §§ 10790)(2)(institutional providers), (h)(1)(individual health care professional)(citing 42 U.S.C. 1395, *et seq*.). Services and supplies that are not medically or psychologically necessary for the diagnosis or treatment of a covered illness or injury are specifically excluded from coverage. 32 C.F.R. § 199.4(8)(1).

26. TRICARE/CHAMPUS prohibits improper billing practices such as unbundling, fragmenting, code gaming, and duplicate billing as a means of manipulating CPT codes to increase reimbursement. 32 C.F.R. §§ 199.9(c). Such practices are considered fraudulent and abusive and a misrepresentation of services. 32 C.F.R. §§ 199.9(c)(5) - (c)(8).

D. Medicaid Program

27. Medicaid is a joint federal-state program that provides health coverage or nursing home coverage to certain categories of care assisted individuals. 42 U.S.C. § 1396-1. Congress and CMS set out general rules under which Medicaid operates. Each state runs its own program.

Medicaid is partially funded by federal funds and partially funded by state funds. 42 U.S.C. § 1396(a). Eligibility for Medicaid is largely determined by income. Each state must operate its own Medicaid system, but that system must conform to federal guidelines in order for the state to receive matching funds and grants. In Illinois the Medicaid system is administered by the Department of Heath Care and Family Services ("HFS").

E. Medical Coding

28. The American Medical Association assigns and publishes numeric codes, known as Current Procedural Terminology (CPT) and Health Care Financing Administration Procedure Coding System (HCPCS). The codes are a systematic listing of procedures and services performed by health care providers. They include codes for radiation oncology and related services, based on complexity, supervision, and documentation requirements. Health care providers use CPT and HCPCS codes to describe and evaluate the services for which health care providers claim payment. Healthcare benefit programs use these same codes to decide whether to issue or deny payment. Each healthcare benefit program establishes a fee reimbursement for each procedure described by a CPT or HCPCS code.

29. Each year Medicare publishes a Physician's Fee Schedule in which all of the CPT codes are listed together with the reimbursement Medicare allows for each code. Medicare lists the amount of reimbursement paid in the facility setting (i.e., hospital) and the non-facility setting (i.e., office).

30. As a condition of participation in the Medicare Part B program, providers agree to be familiar with, and abide by, the program's reimbursement policies. In particular, Vantage certified to the following requirements when it applied for Medicare enrollment:

> (3) I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.
>
> (5) I agree that any existing or future overpayment made to the supplier by the Medicare program may be recouped by Medicare through the withholding of future payments.
>
> (6) I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity."

31. Vantage, its employees, and Dr. Kabre had a duty to be knowledgeable of the statutes, regulations, and guidelines regarding coverage for Medicare services, which include the policies relevant to radiation oncology and related services.

32. Vantage employees and physicians, including Dr. Kabre, certified that they were knowledgeable of Medicare's requirements in provider enrollment forms submitted.

33. Medicare covers, and participating providers agree to submit, claims only for services that are medically necessary to diagnose and treat illness or injury, and for which the provider maintains adequate supporting documentation, such as physician's orders, medical necessity notes, and other pertinent documentation justifying the treatment administered. 42 U.S.C. § 1395y(a)(1)(A). A physician may not be reimbursed by Medicare for unreasonable or medically unnecessary services.

34. Absent certain exceptions, Medicare Part B does not cover, and providers agree not to submit, claims for services provided that are not necessary, not appropriately administered, or not properly documented.

35. In order for Defendants to be properly reimbursed for patient care by the Medicare program, TRICARE or Medicaid, CMS requires that the treating physician order the applicable services, appropriately administer those services, appropriately document the justification and administration of those services, submit only those codes that correlate with the notes made by the physician in the medical record, and adhere to coding guidelines when assigning applicable codes.

V. VANTAGE'S RADIATION TREATMENT MODALITIES

36. Radiation therapy uses high-energy radiation to kill cancer cells by damaging the DNA in cancer cells so that they cannot repair or reproduce. Patients can receive radiation therapy in two ways, either externally or internally. Internal radiation is referred to in the industry as brachytherapy. Radiation therapy is less invasive than other cancer treatments making it an attractive option for men and women who want to maintain their lifestyles and jobs while receiving treatments. When a physician determines that radiation therapy may be a treatment option for his or her patient, a referral is made to a radiation oncologist. Oncologists at Vantage are the beneficiaries of these physician referrals.

37. Vantage utilizes radiation therapy in a series of different modalities. During external beam radiation, a beam of radiation is directed to the tumor and immediate surrounding area in order to destroy the tumor and any nearby cancer cells. Internal radiation or brachytherapy is the placement of radioactive sources in or next to a tumor. Because the

radiation sources are placed so close to the tumor, doctors can deliver a large dose of radiation directly to the cancer cells with minimal exposure to the normal tissue.

38. At Vantage, patients can be administered several different types of radiation treatment depending on the complexity and location of the tumor. Treatment plans require a detailed evaluation of the tumor and the patient's anatomy. As such, the CPT codes affiliated with radiation oncology require detailed documentation and specific physician supervision.

39. One method of treatment used by Vantage in administering radiation therapy is identified as Image Guided Radiation Therapy ("IGRT"). IGRT is used externally by Vantage to help accurately deliver radiation therapy in the treatments of cancer. The use of repeat imaging during the course of the radiation treatment is to enhance accuracy and the precision of the radiation delivery. The physician can image the target before or during the delivery of radiation treatment while the patient is laying on the treatment table. These images will be compared with original simulation images. IGRT involves conformal radiation treatment guided by imaging such as CT, x-ray or ultrasound taken in a treatment room before or during treatments. It is commonly used with Intensity Modulated Radiation Therapy ("IMRT").

40. A second modality utilized by Vantage and its radiation oncologists is IMRT. IMRT involves the use of multiple high-energy external x-ray beams to target the tumor. The radiation beams are calculated in advance as part of a patient specific treatment plan to deliver precise radiation while minimizing the dose to the normal surrounding tissues. The strength of the beams can be adjusted as necessary depending on the size, location and stage of the cancer. IMRT is a more complicated treatment than normal external treatment. Before planning the treatment to be utilized for a patient, a physical examination and medical history review must be

conducted. This treatment requires direct supervision by a radiation oncologist in order to obtain payment from CMS.

41. A third treatment involves seed implants (Low Dose Rate Brachytherapy). Seed Implant Brachytherapy involves the use of tiny radioactive isotopes called "seeds" that are permanently placed in the body. This form of treatment controls the dose and reduces exposure to the normal healthy tissues that surround the tumor. The relative amount of radiation is very low and over a period of time, implanted seeds lose their radioactivity and can remain in the body. In the early stages of prostate cancer for example, seed implantation is often used as a stand alone treatment. A prostate seed implant may be utilized unilaterally for treatment or as additional treatment in conjunction with moderate doses of external beam irradiation. The prostate seed implant procedure is a multi-step process that is typically completed primarily by a radiation oncologist with the assistance of urologist.

42. It is essential that postimplant dosimetry be performed on all patients undergoing permanent prostate brachytherapy. Dosimetry is the calculation of the absorbed dose in tissue resulting from the exposure to ionizing radiation seeds. The dose distributions following implantation are never exactly the same for each person as those planned prior to the implant. Because the dose distributions may differ ever so slightly, it is important to document the actual dose that the prostate and normal adjacent tissues will receive over the life of the implant. This can only be determined if a postimplant dosimetric assessment is performed.

43. Either x-rays or CT simulation films followed by 3D simulation and reconstruction are obtained following implantation (about 30 days post implant) to verify that the final seed array meets that specified in the treatment plan. The final seed array is then subject to

computer brachytherapy isodose calculations to ensure that the prostate receives the desired dose radiation.

44. The information obtained from postimplant dosimetry is essential for optimal patient care. Significant over-dosing of the prostate may increase the risk of side-effects. Significant under-dosing of the prostrate can lead to treatment failure. Therefore, the federal government has determined that any results which demonstrate a variation of 20 percent of the proposed coverage area versus the actual area in the implantation of the radioactive seeds is an immediate reportable medical event to the Nuclear Regulatory Commission ("NRC") that a provider must make within 24 hours of discovery of the failed treatment.

45. At the conclusion of the course of treatment, a written summary of the treatment delivery parameters is generated, including the total dose of brachytherapy and the total dose of external beam therapy, if it is given, treatment technique, treatment volume, acute side effects, clinical course, and patient disposition. Patients treated with brachytherapy must be evaluated after treatment at regular intervals by the radiation oncologist for response and early and late effects on normal tissues by the radiation.

VI. VANTAGE'S FRAUDULENT ACTIVITIES

46. As a medical physicist, Plaintiff was working mainly at the Spring Valley and Streator Centers. Plaintiff has firsthand knowledge of the fraudulent practices by Defendants at these locations. Plaintiff became familiar with the operations and practices of other Vantage Centers through temporary coverage by him at these locations, through orientation, and by talking to co-employees and staff members located at the other Vantage Centers. Accordingly, Plaintiff has direct knowledge of the practices at Spring Valley and Streator, along with the

Centers located at South Suburban Cancer Center, Hazel Crest, Illinois; Imperial Valley Cancer Center, El Centro, California; Riverside Radiation Therapy Center, Riverside, California; St. Bernardine Radiation Therapy Center, San Bernardino, California; Redhawk Radiation Therapy Center, Temecula, Brooklyn; Radiation Oncology; Northern Boulevard Radiation Oncology, New York; and Evansville Cancer Center, Indiana.

47. From prior to November 2008 through at least September 2010, Defendants have defrauded the United States by knowingly submitting and knowingly causing false or fraudulent claims for improper and unjustifiable radiation oncology services to be submitted to federal health care programs and state Medicaid programs.

48. These unlawful activities by the Defendants damaged the United States and the State of Illinois and other state Medicaid programs by causing them to pay more to Defendants than the amounts to which they were actually entitled.

49. Defendants routinely billed for services without providing the necessary supervision, without rendering the service for which the United States was billed, without including the necessary documentation to support the code, and for services that were inappropriately administered.

50. The federal health care programs, the State of Illinois and other applicable states paid millions of dollars to Defendants that should not have been paid.

51. Despite the relevant CPT codes' explicit parameters that Defendants must follow in billing for procedures they performed, Defendants knowingly failed to administer the services properly in violation of Medicare guidelines for the specific purpose of increasing their billings and revenue.

A. Defendants' Submission For Payment Relating To Patients Who Received Improper Doses Of Radiation.

52. During the course of Plaintiff's employment, Plaintiff became aware of numerous occasions where Defendants billed Medicare and Medicaid for radiation services provided to patients that were inappropriately administered.

53. The regulations set forth under 10 C.F.R. 35.3045 provide that Vantage is required to report to the NRC treatment to a patient that triggers a medical event. Specifically, 10 C.F.R. 35.3045(a) mandatorily requires Vantage:

> "(a) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in--
>
> (1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and
>
> (i) The total dose delivered differs from the prescribed dose by 20 percent or more;
>
> (ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
>
> (iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more."

54. During the year 2008 and thereafter, patients regularly received inappropriate doses of radiation that were administered by Vantage and/or Dr. Kabre for patients undergoing brachytherapy that differed from the prescribed doses of radiation for each patient.[3] Upon

[3] Relator believes this failure to follow federal law in refusing to report brachytherapy

discovery of the administration of the inappropriate doses, Vantage was required to report this event to the NRC. The report as required under 10 C.F.R. 35.3045(c) and (d) was to be made to the NRC Operations Center the following calendar day after discovery of the medical event, and thereafter a written report submitted to the NRC Regional Office within 15 days after the discovery of a medical event.

55. The patients who received the federally prohibited doses have been identified, but are not listed in the complaint in order to protect their privacy. During the year 2008 they number at least 19 patients at Streator and Spring Valley. The discovery of the prohibited doses for these patients occurred during the post implant dosimetric assessment.[4] The identity of these 2008 patients and the dates of the dosimetric treatment identifying a variation of at least 20 percent between the pre-implantation prescription for radiation dosage seeds and the post-implant dosimetric assessment in violation of the federal regulations will be revealed once appropriate precautions are taken under HIPPA.

56. Vantage and Kabre knowingly billed the United States for these services even though the patient was inappropriately treated. The CPT codes associated with these procedures under evaluation and planning are: 77470, 77328, 77300, 77331 (technical billing); 9924x, 77263, 77470, 76873, 77328, 77300, 77331 (professional billing); and 9924x, 77263, 77470, 76873, 77328, 77300, 77331 (global billing). The CPT codes associated with these procedures

---

negative medical events has been going on since 2002.

[4] Most recently the NRC fined the VA Medical Hospital in Philadelphia almost $227,500 for 8 violations of NRC requirements in failing to report a radiological medical events that resulted in nearly 100 medical errors. The history and findings of the NRC can be accessed at www.NRC.gov/reading-rm/doc. The identification of the activities at Vantage in failing to adhere to the applicable regulatory guidelines is much worse and far greater in terms of number of reportable events then that which occurred in Philadelphia.

under application are: 76000, 77332, 77778, 77790, 77370, C1718, C1720, C1728, C1715 (technical billing); 55859, 76965, 76000, 77332, 77778, 77790 (professional billing); and 55859, 76965, 76000, 77332, 77778, 77790, 77370, Q3001, 99070 (global billing). The CPT codes associated with these procedures under post implant are: 76370, 77295, 77336 (technical billing); 77295 (professional billing); and 76370, 77295, 77336 (global billing). The CPT codes associated with these procedures under standard brachytherapy are: 77290, 77328, 77336 (technical billing); 77290, 77263 (professional billing); and 77290, 77328, 77336 (global billing).

57. In addition to the foregoing patients, in December 2008, Patient X was implanted with almost 170 percent of the prescribed dose of radiation. This dose was to be followed up with external beam radiation of an additional 50 percent of the prescribed dose. Thus, this patient received 1.7 times the prescribed dose of radiation. This inappropriate treatment also violated the NRC regulations and was not medically necessary under CMS rules and regulations, and therefore was not reimburseable.

58. With respect to Patient X, Plaintiff forwarded by electronic mail this reportable medical event on December 12, 2008 to the Vantage administration, including Dr. Kabre and Dr. Aissi, who at the time was the Vice President of Medical Physics for Vantage. A copy of an email corroborating this report is attached hereto and incorporated as Exhibit “A”. Vantage and Dr. Kabre chose to purposely cover up and not report this incident to the NRC and instead billed for the treatment under Dr. Kabre’s pin number.

59. These are not the only patients who received an inappropriate dosage of seed radiation through brachytherapy. Significant numbers of patients throughout the Vantage system have also received inappropriate doses of radiation each of which constitute a medical event

which has not been reported to the NRC. Vantage agreed in the presentation of its claims for payment to CMS to refrain from knowingly billing the United States for inappropriate treatment or treatment that is medically unnecessary. Knowingly submitting bills to CMS which are fictitious, materially false or fraudulent in the connection to or delivery of, or payment for healthcare services constitutes a false claim for which the United States is entitled to damages.

60. In 2009 the Defendants actively engaged in altering the records so that the inappropriate doses of seed radiation to their patients would not be reflected in the medical record for the patient, and the medical records for those patients would not reflect that a medical event did occur. Therefore those medical events were not reported to the NRC. When the patients' medical records showed the actual reportable event because of inappropriate treatment, a second set of records for each patient was changed by having Dr. Kabre at a later date dictate notes to reflect the change in results. In short, Defendants maintained two sets of medical records for numerous patients. The patients for whom the results of the radiation treatment were changed are known, but have not been included in order to protect their privacy.

61. Dr. Kabre and Vantage upper management, including Dr. Aissi, discussed the seed implant violations on numerous occasions. In late 2009 Kabre sent numerous patient records to Dr. Aissi for review and input. On October 21, 2009, Plaintiff offered to have an independent peer review of the records. A copy of the email corroborating this request is attached hereto as Exhibit "B" and incorporated by reference. Subsequent to receiving the email, Dr. Kabre telephoned Plaintiff on two to three occasions verbally reprimanding him for requesting the peer review in writing.

62. Subsequent to the Defendants' treatment of the patients who received

inappropriate doses of radiation, the Defendants knowingly submitted electronic claims to WPS for payment from the United States and CMS relating to the treatment of these patients while representing that these patients had been appropriately treated when in fact they had not.

63. The claims for payment were knowingly false because the services provided on which the claims were based were not appropriately administered and/or were improperly documented and/or were fraudulently submitted in violation of the FCA.

B. Defendants Failed To Supervise Radiation Treatment And Patient Care For IGRT Radiation Treatment.

64. The administration of radiation therapy requires specific supervision. Failure to render that supervisory care makes such services non-reimburseable by CMS because they are medically unnecessary. 42 C.F.R. § 411.15(k)(1).

65. Defendants systematically administered an Image Guided Radiation Therapy or IGRT procedure to its patients without the required level of physician supervision.

66. 42 C.F.R. § 410.32(b) sets forth the requirement that diagnostic tests are not reasonable and necessary, and hence are not payable, unless they are performed under the appropriate level of supervision by a physician. Specifically, that provision provides:

> "(b) Diagnostic x-ray and other diagnostic tests -- (I) Basic rule. Except as indicated in paragraph (b)(2) of this section, all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act [42 U.S.C. § 1395x(r)]. Services furnished without the required level of supervision are not reasonable and necessary (see § 411.15(k) (I) of this chapter)." (Emphasis added).

42 C.F.R. § 410.32(b)(3) sets forth three different levels of physician supervision, general, direct, and personal, and they are defined as follows:

> "(i) General supervision means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the non-physician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.
>
> (ii) Direct supervision in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.
>
> (iii) Personal supervision means a physician must be in attendance in the room during the performance of the procedure.

67. IGRT allows physicians to more precisely target the delivery of radiation to affected areas and it only became eligible for Medicare reimbursement in 2006. At the time these services were rendered, the CPT code for IGRT, CPT 77421, required personal supervision, which means the "physician must be in attendance in the room during the performance of the procedure." 42 C.F.R. § 410.32(b)(3)(iii). Prior to January 1, 2009, all IGRT tests were required to be performed under the personal supervision of a physician, and subsequent to January 1, 2009, the tests were to be performed under a physician's direct supervision.

68. In utilizing IGRT, a patient is placed on the treatment unit where he is subjected to imaging procedures such as CTs, KV or MV x-rays. These tests are performed in a treatment room just prior to the patient receiving his or her daily radiation therapy treatment. After the images are reviewed, the patient's position is adjusted as necessary to allow for the precise delivery of radiation to the tumor while minimizing the amount of radiation delivered to adjacent body areas. Prior to January 1, 2009, the images were to be reviewed by a physician before the delivery of the radiation to the tumor.

69 Plaintiff has firsthand knowledge of Vantage's practices with respect to the IGRT procedures performed at Spring Valley and Streator. On any given day, approximately 20 IGRT procedures were performed at these two Centers. Most of these treatments were billed to Medicare or Medicaid. The approximate number of daily IGRT procedures performed at all Vantage locations exceeds 400.

70. While using the CPT Code 77421 and prior to January 1, 2009, Vantage rarely had a physician present in the treatment room during an IGRT procedure. Subsequent to January 1, 2009, it was rare for a physician to be in the same building while the procedure was being performed. In fact, it was rare for a physician to be present at the Streator address on a Wednesday while the IGRT's were being performed at that location during that day of the week. This lack of supervision existed throughout the Vantage radiation centers, including but not limited to the Vantage center in El Centro, California wherein Dr. Farah Ramez was the medical oncologist responsible for ensuring that appropriate supervision for the radiological procedures occurred.

71. To create the illusion that radiology oncologists were providing real time supervision, Vantage used third-party remote party access software. The software through the internet gotomypc.com does not satisfy the explicit requirement of being in the room where the procedure is administered or even in the same office. The system, as designed, did not allow for physician supervision prior to the administration of treatment.

72. Vantage normally had the IGRT procedures performed by radiation therapists with no real time involvement from a radiation oncologist. For example, the therapist after taking the x-ray images in the treatment area would write on a sheet that they performed the x-ray. Rarely

did the oncologist attend or review the images. On most occasions it was a common practice that the radiation oncologist signed the IGRT sheet once or twice a week without reviewing the images prior to treatment. The therapist would fill out an information sheet on a tabulated form and then check the tabs or line on the document to confirm the therapist's activities.

73. CMS requires specific documentation in the patient's record corroborating the administration of the appropriate physician supervision on the day of the treatment. Services that are not performed under the appropriate supervision are not considered reasonable and necessary and therefore are not covered under Medicare. 42 C.F.R. 410.32 (b); 42 C.F.R. 410.32(d)(2).

74. Invariably, the therapist would proceed with the radiation treatment for the patient without the physician having reviewed the prior set of images, being available in the room, or in the same building location. The images obtained using the IGRT procedure would be reviewed by the radiation oncologist only after the treatment was completed or not at all. Frequently the radiation oncologist would be unavailable and not present in the building while the procedure was being performed. On these occasions the treatment records would be signed days later by the physician oncologist including Dr. Kabre.

75. For example, Dr. Kabre was on vacation from December 1, 2008 through at least December 23, 2008, and from November 2009 through December 2009. During this period of time Vantage submitted bills for services to the United States relating to Code 77421 for Dr. Kabre while Dr. Kabre was out of the country or on vacation. Therefore, she could not have provided the appropriate supervision for the patients for which IGRT procedures were performed.

76. Plaintiff regularly reviewed patient's charts weekly and bi-weekly and rarely was the IGRT certification completed with the appropriate supervision while the procedure was being

performed by the therapist or on the day the services were rendered.

77. The failure to provide appropriate physician supervision to patients undergoing IGRT's is memorialized on numerous compliance alerts and compliance review summaries conducted by Vantage on an in-house basis. For example, in a memorandum dated February 24, 2009 from Nicki Valero, she noted in a sample of patient files numerous deficiencies relating to the Vantage billing to CMS. (Attached as Exhibit "C" hereto and incorporated by reference). For example, Valero noted:

> "5. IGRT must be charged out using the name of the physician who was in the office supervising and signing off of the shift/image. Virtual review outside the office where the service was performed does not meet the supervision requirements of IGRT." (Emphasis added).[5]

On February 10, 2009, Vantage identified the problem with billing IGRT under Code 77421 when physicians were not in the office. Specifically, the compliance department found 17 separate problems in a sample of just 12 patient charts at the Spring Valley center. One of the issues raised by the compliance department also related to the IGRT supervision requirements:

> "11. X-ray based IGRT 77421 must be billed globally or not at all. Doctor must sign off on the shift/image daily for the code to be charged. The Shift Sheet demonstrates the physician only signed off weekly. The technical component of 77421 has a supervision level "3" meaning in direct attendance and the documentation must support this level of supervision.
> Corrective Action
> • Review supervision and documentation requirements for 77421" (Emphasis added).

[5] Under the IGRT Guidelines attached as Exhibit "C", the compliance office reminded Vantage personnel that CPT code 77421 requires the physician to sign the patient records and documents daily to bill the code. If the doctor does not sign the daily/shift image, Vantage may not charge for the technical or the professional component associated with this procedure. (Exhibit "C", IGRT Guideline).

(Attached as Exhibits "C" and "D" herein). The foregoing is only a sample of the compliance deficiencies identified by Vantage's compliance officer detailing the submission of bills while failing to properly supervise and/or document the necessity of IMRT radiation therapy.

78. Defendants' failure to supervise the administration of IGRT despite knowledge of their non-compliance resulted in the knowing submission of millions of dollars of false claims to federal and state health care programs for payment relating to claims that were medically unnecessary under 42 C.F.R. § 410.32(b)(3) and 42 C.F.R. § 411.15(k)(1).[6]

C. Defendants Administered Intensity Modulated Radiation Therapy (IMRT) And Submitted False Claims For These Tests. (CPT Codes 77301 And 77418).

79. IMRT differs from conventional therapy in that it shapes radiation beams to closely approximate the size of the tumor being treated. The intensity of the radiation in IMRT can be changed during treatment to spare damage to the adjoining normal tissue than that which occurs during conventional radiation therapy. Accordingly, the professional and technical billing of IMRT requires direct supervision — "the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure." See 42 C.F.R. § 410.32(b)(3)(ii). Where direct or personal supervision is required, physician supervision at the specified level is required throughout the performance of the test. 42 C.F.R. § 410.32(b)(3).

80. IMRT is therefore indicated in situations in which extremely high precision is

---

[6] The failure to document the necessity for a procedure and subsequently billing Medicare is also apparent during the performance of the prostate seed implant procedure wherein Ms. Valero writes: "No procedure note in file to support prostate seed implant charges 77778 and 77790." (Exhibit "D", #16). These are not reimburseable under Medicare.

required.

81. Where such high precision is not required, conventional radiation therapy may achieve the same or better results at significantly lower cost. IMRT is billed using various CPT codes, including 77301 and 77418.

82. On numerous occasions the Plaintiff and Vantage's own compliance department advised Vantage and its physician employees, including Dr. Kabre, that submissions of bills relating to services performed for IMRT's were not in compliance with Medicare supervision requirements. Nevertheless, Vantage and Kabre submitted bills to IMRT providers without being present in the office and immediately available to furnish assistance and direction throughout the performance of the procedures.

83 Because IMRT is significantly more expensive than conventional radiation therapy, physicians have a financial incentive to utilize IMRT in situations where other treatment methods may achieve the same or better results. Consequently, Medicare has placed limits on when IMRT may be used, and has required those physicians to document in the patient's medical record the reasons why IMRT is necessary.

84. Vantage was aware of these provisions in part due to the requirement that it must follow the Local Coverage Decision ("LCD") issued by WPS and applicable to Vantage when submitting bills for charges incurred by patients to CMS. (Attached as Exhibit "E").[7] The LCD dictates that IMRT is not a replacement therapy for conventional and 3D conformal radiation therapy methods. Vantage was also aware of the guidelines as set forth in its compliance report of February 24, 2009. (Exhibit "C", "IGRT Guidelines").

[7] The LCD attached is the most recent issued by WPS. The standards identified in this version are virtually if not the same as earlier versions.

85. According to the LCD, IMRT is only considered reasonable and necessary in instances where sparing the surrounding normal tissue is of added benefit and at least one of the following conditions is met:

- The target volume is in close proximity to critical structures that must be protected.
- The volume of interest must be covered with narrow margins to adequately protect immediately adjacent structures.
- An immediately adjacent area has been previously irradiated and abutting portals must be established with high precision.
- The target volume is concave or convex, and critical normal tissues are within or around that convexity or concavity.
- Dose escalation is planned to deliver radiation doses in excess of those commonly utilized for similar tumors with conventional treatment.

86. Additionally, according to the LCD and CMS a physician that utilizes IMRT radiation therapy must document the indications for IMRT and consider the specific criteria in the documentation which provides the basis to use and charge for this therapy.

87. Accordingly, in order to be reimbursed for charges relating to IMRT radiation therapy, not only must Vantage adhere to the proper level of supervision, but the medical record for the specific patient in which IMRT radiation therapy is utilized must include:

a. the reasonable and necessary requirements as outlined under the coverage and limitations sections of the LCD,

b. a defined set of goals and requirements of the treatment plan,

c. a statement by the treating physician documenting the special need for performing IMRT on the patient in question,

d. a signed IMRT inverse plan that meets prescribed dose constraints for the planning target volume (PTV),

e. the target verification methodology which must include the following:

i. documentation of the clinical treatment volume (CTV) and the planning target volume (PTV),

ii. documentation of immobilization and patient positioning,

iii. means of dose verification and secondary means of verification,

iv. independent basic dose calculations of monitor units have been performed for each beam before the patient's first treatment,

f. documentation of fluence distributions (re-computed and measured in a phantom or dosimetry measuring device) is required, and

g. identification of structures that traverse high-and-low-dose regions created by respiration is indicated. Voluntary breath-holding alone is not a satisfactory solution for accounting for organ motion. (Exhibit "C") (Exhibit "F").

88. Vantage and its oncologists, including Dr. Kabre, are members of the leading oncology society, the American Society for Therapeutic Radiology and Oncology ("ASTRO"). ASTRO continually identified for its members the inherent danger of upcoding billing for IMRT's without the necessary medical documentation backup.

89. For many years, Vantage and Dr. Kabre have systematically overused IMRT rather than the alternative/conventional radiation therapy in a significant number of its patients

regardless of medical necessity. Vantage and its oncologists also failed to provide the direct level of supervision that is required and have routinely failed to document the medical necessity of IMRT usage. Plaintiff has in his possession the names of the patients at Streator and Spring Valley who received IMRT's and IGRT's, but has not identified those herein in order to protect their privacy. Written evidence of the inappropriate and over-utilization of IMRT has been recognized by Vantage in its internal audits. Specially, on February 10, 2009, Ms. Valero, the Compliance Director, noted the deficiency at the Spring Valley and Streator locations. She stated:

> "9. IMRT note of medical necessity needs to specify the critical structures or reason why IMRT was best method for that particular patient compared to 3D per Medicare LCD.
> Corrective Action
> • Review Medicare IMRT policy documentation requirements
>
> 10. Missing documentation of delivery to a phantom for QA of the IMRT plan.
> Corrective Action
> • Review Medicare IMRT policy documentation requirements
>
> . . .
>
> 12. IMRT plans must have an independent MU calc for each beam before the plan is used to treat the patient. If you create an IMRT boost plan you must have documented MU calcs for each of the boost ports to charge the calcs 77300. Patient [name redacted] has the phantom QA for the initial and boost but only independent MU calcs for the initial IMRT plan.
> Corrective Action
> • Review Medicare IMRT policy documentation requirements
>
> 13. Physics consultation performed for QA or verification of the IMRT plan is not allowed as this work is included in the IMRT plan code 77301. Physics consultation may be

> performed with IMRT if request from physician is clearly documented and for a reason other than QA or verification of the IMRT plan.
> Corrective Action
> • Review ASTRO clarification of what is included in IMRT plan code 77301"

(Attached hereto as Exhibit "D" and incorporated by reference). This compliance report is just one of many reports issued by Vantage which highlights Vantage's failure to comply with applicable billing and submission requirements under Medicare thereby rendering the bills and services medically unnecessary and therefore not reimburseable.

90. Most recently, in August 2010, a patient being administered radiation at Streator pursuant to one of the aforementioned procedures died on the Vantage premises. A physician was unavailable at that time to assist in the resuscitation as required under federal law in order to bill for that radiology service.

91. By knowingly submitting claims under CPT codes 77301 and 77418 to the fiscal intermediary and CMS that are false, the Defendants' actions constitute a violation of the FCA. Millions of dollars have been paid by CMS and Vantage for IMRT's that were either not supervised, inappropriately provided, or not appropriately documented and therefore upcoded.

D. Vantage's Improper Billing Requests Under CPT Code 77470 - - "Special Treatment Procedure".

92. In certain cases, physicians performing radiation therapy are required to expend additional work and effort beyond what would normally be expected for a certain procedure. Under those circumstances, the physician may obtain additional payment by billing CPT code 77470 - "Special Treatment Procedure."

93. The use of code 77470 is intended to be the exception, and it is improper to

routinely use the code without specific case-by-case justification. There is no case in which it is routinely used, and therefore, the physician should decide to report CPT code 77470 on a case-by-case basis and document the work effort involved.

94. In order to bill code 77470, the provider must document the medical necessity for such code. It is expected that documentation will be maintained in the patient's medical record to support the medical necessity for this procedure.

95. Vantage physicians for years routinely have billed code 77470 for many radiation patients they treat without providing the necessary documentation in the patient record which justifies the increased billing for CPT code 77470. Vantage's philosophy has essentially been that 77470 is a "tree" code that may be added to any IMRT treatment in order to increase billings.

96. There are numerous patients in which no additional documentation is contained in the patient chart that supports the medical necessity of the use of procedure code 77470.

97. Vantage has continued to knowingly bill code 77470 on many of its IMRT patients, without properly documenting the necessity for such code in the records and receiving payment from the United States for this billing. Without the proper documentation in the patient's record, billing for CPT code 77470 is medically unnecessary and therefore not reimburseable.

98. The knowing submission of claims forms to CMS and its intermediary WPS for payment relating to services by Vantage and Kabare identified under CPT code 77470, which are not medically necessary, constitutes a false claim for which the United States Government is entitled to damages.

E. Improper Billing of CPT 77370 - "Special Medical Radiation Physics Consultation".

99. A qualified medical physicist is a professional who specializes in the application of physics to medicine. Medical physicists may help develop improved imaging techniques, collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location.

100. It is anticipated that a medical physicist will cooperate with the radiation oncologist in preparing a treatment plan for an IMRT patient. In general, the oncologist will assign specific radiation dose requirements and dose constraints, taking into account the tumor volume and location and the surrounding organs. The medical physicist, or a dosimetrist under his supervision, will then use a treatment planning computer to calculate a complex multibeam treatment plan that will deliver the target dose and satisfy the dose constraints. The medical physicist's role under normal circumstances is taken into account in the various payment codes related to IMRT planning and not to be used as a separate charge.

101. In certain circumstances, however, a special problem or circumstance may require the radiation oncologist to request that a qualified medical physicist provide a special consultative report or specific physics service for an individual patient. For example, a patient may have a pacemaker that must be taken into account in developing a treatment plan. In such cases, the physicist will prepare a full consultative report and provide it to the physician, who acknowledges and relies upon the report in providing care to the patient. The provider may obtain additional payment for this special consult by using CPT code 77370.

102. According to the LCD, 77370 is used when the complexity of the treatment plan is of such magnitude that a thorough analysis is necessary to address a specific problem, or when the service to be performed requires the expertise of a qualified medical physicist. The clinical indication that justifies the request for the special physics consultation must be documented, reviewed, signed and dated by a physician. Documentation of the physician's request and the physics report, as well as the physician review of the report, is necessary.

103. Rather than only using the code in special circumstances, however, Vantage has established a policy of billing for a special physics consult for many IMRT patients, regardless of medical necessity. In many cases, the medical record contains no formal request by the oncologist for a special physical consult.

104. Plaintiff has firsthand knowledge of the billing being performed in a false manner as he was the physicist for a significant number of patients for which Vantage billed CPT code 77370 for services that were not sufficiently documented and signed by the physician and therefore medically unnecessary.

105. Vantage's routinely used code 77370 to obtain additional payments for nearly all IMRT patients regardless of the need for a special physics consult is false.

106. Vantage's internal audits identified a practice of improperly and routinely billing code 77370 for its patients. All special physics consult reports are documented via a template and are worded exactly the same for all patients. By definition, special physics reports, 77370, are meant to be customized and "special" for each patient's particular case.

107. Moreover, Vantage has consistently used a new graduate physicist to perform services under CPT code 77370. However, Vantage has used its Vice President, Dr. Aissi, and

his digital signature in billing CPT 77370 for this graduate physicist. Vantage has 34 centers throughout the United States, and it has used Dr. Aissi's digital signature to bill for CPT code 77370 when he was not involved in the care of a specific patient.

108. The knowing submission of claims forms to CMS and its intermediary WPS for payment relating to services identified under CPT code 77370 that were either not performed or were not medically necessary because no medical document exists to support the billing for the extraordinary expenses, constitutes a false claim for which the United States Government is entitled to damages.

F. Improper Billing of CPT 77331 - "Special Dosimetry".

109. This CPT code is used to report the measurement of radiation dose at a given point using special radiation monitoring and measuring devices such as thermoluminescent dosimeters, solid state diode probes, and special dosimetry probes, other dosimetry probes or film dosimetry. This procedure is not to be routinely performed each time the patient is treated. (Exhibit "E", Subsection 5, discussing CPT code 77331). It would be expected that the utilization of this procedure would correspond with the level of complexity of the clinical treatment planning services provided for the patient. This service is typically billed once per port when the physician determines that it is necessary to have a measurement of the amount of radiation that a patient has actually received at a given point, with the final results being utilized to accept or modify the current treatment plan.[8] The monitoring devices utilized for measuring and monitoring can include Thermoluminescent Dosimeters (TLD), solid state diode probes, special dosimetry probes or film dosimetry. (Exhibit "E", Subsection 5, discussing CPT code 77331).

[8] The term port refers to the site on the skin where the radiation beam enters the body.

The physician must specify the type of special dosimetry in order to bill CMS for the procedure. Vantage has systematically used this code inappropriately without having he physician specify the type of special dosimetry to be used.

110. Since January 2010, Vantage has been pressuring their centers to utilize this code for each filed dosimetry. This practice resulted in billing this code for each patient on the average three times rather than a single occasion. Vantage has been instructing staff to take measurements of each field and to repeat the measurement if there are more than one plan for each patient. These unnecessary measurements are without justification and/or performed by unqualified personnel.

111. Vantage also has had physicists sign off on the reports once a week when the reports should be signed off at the time the procedure is performed. The knowing submission of claim forms requesting payment under CPT 77331 for services rendered under this CPT without specifying the type of special dosimetry in the records by a physician is medically unnecessary and therefore is a violation of the FCA.

G. IMRT For Breast Treatment.

112. Vantage has routinely billed CMS and its fiscal intermediary for IMRT procedures relating to breast treatment when the IMRT procedure was either medically unnecessary or inadequate documentation exists in the patient record to justify utilization of this procedure for payment from CMS or its fiscal intermediary.

113. IMRT treatment for breast cancer is not routine. However, it may be indicated when the tumor is in proximity to the heart. In order for a breast IMRT to be medically necessary in lieu of conventional or 3 dimensional radiation, the radiation oncologist must consider the

criteria identified in Exhibit "C" and Exhibit "E", Subsection II, Part D, attached and incorporated herein. Without the memorialization of the consideration of these factors, IMRT for breast therapy is medically unnecessary for which Vantage and Kabre may not bill CMS and WPS.

114. Vantage has knowingly presented bills to CMS and its intermediary using CPT codes 77301 and 77418 requesting payment for services that were never performed or were medically unnecessary because the documentation supporting the use of this procedure for breast treatment is nonexistent.

115. The submission of claims forms to CMS and its intermediary WPS for payment relating to services regarding breast treatment identified under CPT codes 77301 and 77418 that were either not performed, or were not medically necessary, constitutes a false claim for which the United States Government is entitled to damages.

H. Other Upcoding Billing Issues.

116. Although the above practices constitute its most outrageous and routine billing improprieties, Vantage also routinely submits claims that are false for other reasons. Vantage routinely bills for complex simulations under CPT code 77290 without sufficient documentation to justify the level of complexity, and where the simulation should appropriately be billed as a simple simulation under code 77280. Vantage routinely bills electron setups as 3-D simulations under CPT code 77295 when it should almost always be billed under CPT code 77315 which is a lower reimbursement. Documentation of simulation requires a written record of the procedure, a hard copy of the x-ray film, electronic images, and evidence of image review by a physician including his signature or initials, and date reviewed before it may be billed at the higher level.

(Exhibit "E", Subsection B, discussing CPT codes 77280-77295).

117. In addition, Vantage had in its employ a person named Kathleen Peters. Ms. Peters was conditionally accredited by the State of Illinois to provide radiation therapy on behalf of Vantage for its patients.

118. Ms. Peters was only accredited to provide radiation therapy at Spring Valley. A true and accurate copy of Ms. Peters' certificate is attached hereto as Exhibit "F" and incorporated by reference, indicates that Ms. Peters had obtained a conditional accreditation which was only valid for radiation therapy procedures at Spring Valley.

119. Nevertheless, Ms. Peters was directed to provide a substantial number of radiation therapy services at the Streator location where she was not licensed to provide such services.

120. Knowing the limitations on Ms. Peters' accreditation, Vantage submitted bills for services on behalf of Ms. Peters for the radiation therapy activities she performed at Streator when she was not accredited to provide services at that location. Plaintiff is able to identify through medical records Peter's activities at the Streator location.

121. The knowing submission of bills by Vantage for Ms. Peters' activities at Streator was false in violation of federal and state law.

122. Vantage regularly employs radiation therapists who are unqualified to perform the duties of their position. Dr. Kabre as the radiation safety officer is required monitor and ensure the qualified individuals are employed, including ensuring that they receive the appropriate amount of training and orientation. There exists a lack of documentation demonstrating the orientation or training for the radiation therapists, medical dosimetrists or medical physicists at Spring Valley and Streator. For example, Vantage hired an individual named Bryan Jayo as the

manager for Spring Valley and Streator. Mr. Jayo has little or no experience in radiation therapy or billing terminology. Nevertheless, Jayo is the son-in-law of Tommy Hobbs, the Chief Executive Officer of Illinois Valley Community Hospital in Peru, Illinois, which is the planning stages with Vantage of opening a joint radiation therapy treatment center with Vantage in Illinois.

123. Vantage has also been billing the United States for charges relating to x-rays when the x-ray machine has been inoperable.

124. At Spring Valley, Vantage uses an x-ray machine that has not been operational. The use of the x-ray machine for patient care is identified by the term conventional simulation.

125. Vantage has continued to bill the United States under CPT code 77290 at Spring Valley for conventional simulation services that were not performed. This problem was recognized by Ms. Valero in her February 10, 2009, 12 chart review.

> "5. Initial sim note appears that the simulation was performed on s CT in your office. Need to clarify that a "table sim" was performed in your office which includes any markers or immobilization devices and then the patient was sent to the hospital for the CT scan. You should have sim film to back up your simulation note and charge for 77290.
> Corrective Action
> • Investigate if film is actually taken during the table sim and educate on scoring level of sim"

126. The reason there is no sim film available is because one was never taken due to the inoperable machine. Nevertheless, Vantage knowingly billed for these services and collected payment for services not performed. These actions constitute a violation of the FCA.

VII. VIOLATION OF THE FALSE CLAIMS ACT RETALIATION PROVISION

FIRST CAUSE OF ACTION
(Violation of 31 U.S.C. § 3730(h)(1))

127. Plaintiff realleges his allegations in the preceding paragraphs as if fully set forth herein.

128. During the period of Plaintiff's employment, Plaintiff informed Vantage of its fraudulent billing practices and Medicare violations. The most recent discussion prior to Plaintiff's termination occurred on or about May 22, 2010. On that date Plaintiff participated in a telephone conversation with Madjid Aissi, Julia Georgesen and Richard Daversa in which he indicated that Vantage was engaging in fraudulent billing practices which included but were not limited to the issues identified in this complaint. The issues Plaintiff identified to Defendants over the period of 2008 through 2010, including the May 22, 2010 meeting, constitute one or more violations of the False Claims Act.

129. Plaintiff's complaints about Vantage's unlawful billing practices constituted protected activity under the FCA.

130. In retaliation for Plaintiff's complaints Vantage required Plaintiff to undergo a skills test on August 31, 2010 purportedly to test his physicists skills. These are the same skills Plaintiff had exhibited and utilized for almost two years of his employment with Vantage, a result of which Vantage never criticized or disciplined Plaintiff.

131. Subsequently, on September 8, 2010 Plaintiff was provided a letter informing him that he was terminated. The reasons articulated for his termination were:

> "You fail to engage in appropriate professional conduct such as honesty, positive communications, collaboration, and cooperation in order to foster successful professional relationships with team members. On August 31, 2010, a technical skills evaluation was

> conducted by Maung Yoe-Sein and Madjid Aissi, in which your technical skills were found to be deficient with respect to:
>
> - Development of technical knowledge and job related competencies (e.g., you lack appropriate 3D & IMRT treatment planning skills);
> - Development of analytical skills; and
> - Demonstration of appropriate judgment.
>
> These issues are too disruptive to the rest of the team's ability to successfully and appropriately address patient needs. Unfortunately, we are to the point where we collectively believe it is in the best interests of the team and patients for your to be separated from employment at this time."

(Attached hereto as Exhibit "G" and incorporated by reference).

132. The reasons articulated for Plaintiff's termination are pretextual and were offered by Vantage in order to hide its unlawful actions towards Plaintiff.

133. Plaintiff was terminated by Vantage, and upon information and belief Dr. Kabre, because of his complaints about Vantage's unlawful billing practices which constitute a violation of the FCA.

134. Subsequently, on November 29, 2010 Plaintiff filed a False Claims Act case against Vantage.

135. As a result of the materials supplied by Plaintiff to the United States, and the United States' investigation, the United States entered into a Settlement Agreement with Vantage in which Vantage agreed to pay the United States the principle amount of $2,085,000, plus attorneys' fees in the amount of $135,000 in settlement of the allegations asserted by Plaintiff in his False Claims Act complaint. A copy of the Settlement Agreement is attached hereto as Exhibit "H" and incorporated by reference.

136. As a direct and proximate result of the actions of the Defendant, Plaintiff is entitled to all relief as set forth under 31 U.S.C. § 3730(h), including but not limited to, reinstatement, two times the amount of back pay which totals approximately $680,000, a reasonable front pay award for three to five years, special damages for emotional distress, litigation costs and reasonable attorneys' fees.

PRAYER FOR RELIEF

WHEREFORE**,** Plaintiff demands against the Defendants, jointly and severally, for the following relief as set forth under 31 U.S.C. § 3730(h) and as set forth under paragraph 136 of his First Amended Complaint.

DEMAND FOR JURY TRIAL

The Plaintiff demands a jury trial in this case.

RESPECTFULLY SUBMITTED,

/S/ Mark J. Byrne
MARK J. BYRNE (0029243)
JACOBS, KLEINMAN, SEIBEL & MCNALLY
Attorney for Plaintiff
Cincinnati Club Building
30 Garfield Place
Cincinnati, OH 45202
Tele (513) 381-6600
Fax (513) 381-4150
E-Mail: mbyrne@jksmlaw.com

/S/ Robert B. Newman
ROBERT B. NEWMAN (0023484)
NEWMAN & MEEKS CO., LPA
Attorney for Plaintiff
215 E. Ninth Street, Suite 650
Cincinnati, OH 45202
Tele (513) 639-7000
Fax (513) 639-7000
E-Mail: robertnewman@newman-meeks.com

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing has been forwarded to the following by electronic mail, this 2nd day of May, 2014:

Joseph N. Gross, Esquire
Benesch, Friedlander, Coplan & Aronoff, LLP
Attorney for Defendant
Vantage Oncology & Associates, Inc.
200 Public Square, Suite 2300
Cleveland, OH 44114-2378
jgross@beneschlaw.com

/S/ Mark J. Byrne
MARK J. BYRNE (0029243)
Attorney for Plaintiff